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APPLICATION NO.	F	ILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,422		08/10/2001	Gary Van Nest	377882001420	6952
25226	7590	05/01/2003		•	
MORRISON & FOERSTER LLP				EXAMINER	
755 PAGE N			GIBBS, TERRA C		
PALO ALTO, CA 94304-1018					
				ART UNIT	PAPER NUMBER
				1635	13
			DATE MAILED: 05/01/2003		

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.	
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	Applicati n No.	Applicant(s)				
•	09/927,422	NEST ET AL.				
Offic Action Summary	Examiner	Art Unit				
	Terra C. Gibbs	1635				
The MAILING DATE of this communicati n app Period f r Reply	ars on the cover sh et with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). Status	16(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) days fill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE!	rely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133).				
1) Responsive to communication(s) filed on	 ·					
2a) ☐ This action is FINAL . 2b) ☐ Th	is action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims						
4) Claim(s) 1-84 is/are pending in the application	•					
4a) Of the above claim(s) is/are withdraw	vn from consideration.					
5) Claim(s) is/are allowed.						
6) Claim(s) is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) 1-84 are subject to restriction and/or	election requirement.					
Application Papers						
9) ☐ The specification is objected to by the Examine						
10) ☐ The drawing(s) filed on is/are: a) ☐ accept						
Applicant may not request that any objection to the						
11) The proposed drawing correction filed on	_ is: a)	oved by the Examiner.				
If approved, corrected drawings are required in re						
12) The oath or declaration is objected to by the Ex	aminer.					
Pri rity under 35 U.S.C. §§ 119 and 120) (I) (D				
13) Acknowledgment is made of a claim for foreign	n priority under 35 U.S.C. § 119(a	1)-(a) or (t).				
a) ☐ All b) ☐ Some * c) ☐ None of:						
1. Certified copies of the priority document						
2. Certified copies of the priority document						
3. Copies of the certified copies of the prio application from the International Bu* See the attached detailed Office action for a list	reau (PCT Rule 17.2(a)).					
14) Acknowledgment is made of a claim for domesti	c priority under 35 U.S.C. § 119(e) (to a provisional application).				
 a) ☐ The translation of the foreign language pro 15)☐ Acknowledgment is made of a claim for domest 	ovisional application has been rec ic priority under 35 U.S.C. §§ 120	eived.) and/or 121.				
Attachment(s)	_					
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _	5) Notice of Informal	y (PTO-413) Paper No(s) Patent Application (PTO-152)				
C. Detect and Trademody Office						

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DETAILED ACTION

Claims 1-84 are pending in the instant application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-19, 22, 23, 48-65, 68, 69, 70-76, 79, 80, 81 and 82, drawn to an immunomodulatory polynucleotide/microcarrier (IMP/MC) complex comprising a polynucleotide linked to a biodegradable microcarrier (MC) wherein said MC is less than 10 μm in size and a kit comprising said immunomodulatory polynucleotide/microcarrier (IMP/MC) complex, classifiable in class 536, subclass 24.3.
- II. Claims 1, 11, 12, 13, 14, 18, 20, 21, 66, 67, 77, 78, 81, 83 and 84, drawn to an immunomodulatory polynucleotide/microcarrier (IMP/MC) complex comprising a polynucleotide linked to a biodegradable microcarrier (MC) wherein said MC is less than 10 μm in size and a kit comprising said immunomodulatory polynucleotide/microcarrier (IMP/MC) complex wherein said complex further comprises an antigen, classifiable in class 536, subclass 24.1.
- III. Claims 24-43, 46 and 47, drawn to a method of modulating an immune response in an individual comprising administering to an individual a composition comprising an immunomodulatory polynucleotide/microcarrier (IMP/MC) complex comprising a

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polynucleotide linked to a biodegradable microcarrier (MC) wherein the MC is less than 10 μm in size, classifiable in class 435, subclass 4.

IV. Claims 24, 35, 36, 37, 38, 42, 44, and 45, drawn to a method of modulating an immune response in an individual comprising administering to an individual a composition comprising an immunomodulatory polynucleotide/microcarrier (IMP/MC) complex comprising a polynucleotide linked to a biodegradable microcarrier (MC) wherein the MC is less than 10 μm in size, wherein said composition further comprises an antigen, classifiable in class 435, subclass 7.22.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I and II are unrelated, each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions of Groups I and II are unrelated and distinct because they employ different molecules with different chemical and physical structures so that independent searches of the prior art would be required that would constitute a serious burden on the Examiner. For example, a search of the immunomodulatory polynucleotide/microcarrier (IMP/MC) complex of Group I would not encompass all of the art relevant to the immunomodulatory polynucleotide/microcarrier (IMP/MC) complex, wherein said complex further comprises an antigen of Group II. They are materially distinct compositions which differ in antigen complexity. The differences between Inventions I and II are further underscored by

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their different classifications and independent search status. Thus, they are unrelated and patentably distinct from each other.

Although the methods of Groups III and IV are related because they encompass a method of modulating an immune response in an individual comprising administering to an individual a composition comprising an immunomodulatory polynucleotide/microcarrier (IMP/MC) complex comprising a polynucleotide linked to a biodegradable microcarrier (MC) wherein the MC is less than 10 µm in size, they are patentably distinct from each other. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to related methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: They employ different molecules with different chemical and physical structures so that independent searches of the prior art would be required that would constitute a serious burden on the For example, a search of the immunomodulatory polynucleotide/microcarrier Examiner. (IMP/MC) complex of Group III would not encompass all of the art relevant to the immunomodulatory polynucleotide/microcarrier (IMP/MC) complex, wherein said complex further comprises an antigen of Group IV. They are materially distinct methods which differ in reagents and/or dosages and/or schedules used, response variables, criteria for success, and antigen complexity. The differences between Inventions III and IV are further underscored by their different classifications and independent search status. Thus, they are unrelated and patentably distinct from each other.

Inventions of Groups I and II are related to the method inventions of Groups III and IV as product and process of use. The inventions can be shown to be distinct if either or both of the

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following can be shown: (1) the process for using the product as claimed can be practiced with

another materially different product or (2) the product as claimed can be used in a materially

different process of using that product (MPEP § 806.05(h)). In the instant case the products can

be used in materially different processes of use. For example, the immunomodulatory

polynucleotide/microcarrier (IMP/MC) complex of Groups I and II can be used as a

hybridization probe, which is a materially different process than a method of modulating an

immune response in an individual comprising administering to an individual a composition

comprising an immunomodulatory polynucleotide as in Groups III and IV.

Because these inventions are distinct for the reasons given above and have acquired a

separate status in the art as shown by their different classification and have acquired a separate

status in the art because of their recognized divergent subject matter, restriction for examination

purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an

election of the invention to be examined even though the requirement be traversed (37

CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the

inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a petition under 37

CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is (703) 306-3221. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

tcg April 25, 2003

> RAM SHUKLA PRIMARY EXAMINER